

C. Remarks

1. Status of the Claims

The claims are 1, 2, 7-18, 20-25, 28-30 and 34, with claims 1, 2, 11, 24, and 34 being in independent form. Claim 8 and claim 34 have been amended. Favorable reconsideration is respectfully requested.

2. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 8 stands rejected under 35 U.S.C. §112, second paragraph. The word “about” has been deleted from claim 8, which is believed to overcome the rejection. For the record, applicants disagree with the rejection. “Below about 20%” has a customary and ordinary meaning that would be understood by one of ordinary skill in the art. For example, contrary to the statement in the Office Action, one of ordinary skill in the art would understand that 2% starch is both “less than 20%” and “less than about 20%” starch.

Claims 12, 13, 16-18 and 23 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner has alleged that claims 12, 13, 16 and 17 do not have an antecedent basis for the phrase “the stomach pH.” Applicants respectfully traverse this rejection and point out that the phrase in question is indeed recited in claim 34 at line 3. It is also recited in independent claim 11, from which claims 12, 13, 16 and 17 also depend, at line 3. Accordingly, Applicants respectfully request that the rejection be withdrawn.

3. Rejections Over the Prior Art

A. Lambert

Claims 1, 2, 8 and 9 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Lambert et al. (U.S. Patent No. 6,284,265). Applicants respectfully traverse. The Examiner asserts that the carrier disclosed in Lambert with ground wheat or rolled oats or

mixtures thereof meets the limitation of 15-70% fibre in claims 1 and 2. There does not appear to be any disclosure in Lambert that the antacid composition contains any chopped fibre, and the Examiner makes no citation of any passage disclosing chopped fibre. Since present Claims 1 and 2 require the presence of chopped fibre, these claims (and dependent claims 8 and 9) are not anticipated by the disclosure of Lambert.

Claim 11 stands rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by, or alternatively under 35 U.S.C. § 103(a) as allegedly being obvious over, Lambert et al. Applicants respectfully traverse.

The Examiner acknowledges that Lambert does not specifically teach treatment or amelioration of animal stereotypy, but alleges that the antacid composition of Lambert would inherently treat or ameliorate animal stereotypy. Alternatively, the Examiner asserts that it would be prima facie obvious to expect that reduction in acid levels of the stomach would produce the expected treatment or amelioration of stereotypy in a horse.

It has been pointed out to the Examiner in several of the Applicants' previous responses that there is no disclosure in the cited prior art of a link between stomach acidity and animal stereotypy, and the Examiner has failed to demonstrate any such link known in the prior art. In the absence of any such link, it was not prima facie obvious at the time of the invention to expect that reduction in acid levels of the stomach would treat or ameliorate animal stereotypy.

A limitation may be inherent if it is the "natural result flowing from" the explicit disclosure of the prior art. Eli Lilly & Co. v. Barr Labs., Inc., 252 F.3d 955, 970 (Fed. Cir. 2001). "[W]hen considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art filed at the time of the prior art disclosure." Perricone v. Medicis

Pharm. Corp., 432 F.3d 1368 (Fed. Cir. 2005). In Perricone, the court found that a claim directed to a method of treating sunburn by topically applying the claimed composition to "the skin sunburn" was not inherent in the prior art that disclosed topically applying the composition to skin. The court reasoned that skin sunburn is not analogous to skin surfaces generally, and that the Perricone claim was patentable, as it recited a new use of the composition disclosed by the prior art, i.e., the treatment of skin sunburn. Analogously, administering antacid to a healthy animal, or an animal suffering from stereotypy, is not "inherent" in treating an animal suffering from excess gastric acid secretion.

It is not the case that treatment of animal stereotypy inherently results from practicing the disclosure of Lambert. The antacids in Lambert are given to horses suffering from a specific malady, i.e., excess gastric acid secretion. In contrast, claim 11 recites minimizing the risk of an animal developing stereotypy by orally administering the claimed composition to animals, which may be healthy animals. It is not a "natural result flowing" from the disclosure of Lambert that a healthy animal is prevented from developing stereotypy, as such animals (according to Lambert) would not have been treated. Since the cited art does not recite all the claim elements either explicitly or inherently, claim 11 is not anticipated by the cited art.

Obviousness based on inherency has been found where a claimed method is "generically encompassed by the prior art." See, e.g., In re Woodruff, 919 F.3d 1575 (Fed. Cir. 1990). In Woodruff, the claimed method directed to the method of preventing fungal growth in vegetables was found obvious based on the disclosure in the prior art of preventing deterioration of leafy vegetables. The present case is distinguished from the situation in Woodruff, because the present claims directed toward the treatment or amelioration of animal stereotypy are not generically encompassed by disclosure related to the treatment of excess gastric acid secretion or

gastric ulcer in horses. Claim 11 is not obvious in view of Lambert as animals suffering from stereotypy do not necessarily exhibit the maladies discussed in the reference, i.e., excess gastric acid secretion. They are directed toward the treatment or amelioration of animal stereotypy, a separate indication, which is not generically encompassed by disclosure related to the treatment of excess gastric acid secretion in horses.

Claims 11-17, 23-25 and 28-30 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Lambert et al. (Office Action, pages 9-10). Claims 12-17, 23, and 28-30 are patentable over Lambert at least because they depend from claim 11, which is allowable over Lambert, as argued above. Claims 24-25 recite treatment or amelioration of animal stereotypy, or of minimizing the risk of an animal developing stereotypy by minimizing or reducing ulcer formation. Because there was no connection between ulcer formation and stereotypy taught in the prior art prior to Applicants' priority date, the claimed method is allowable for similar reasons as set forth above in connection with claim 11.

B. Winskill

Claims 17, 19, 28-30 and 34 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by or alternatively under 35 U.S.C. § 103(a) for allegedly being obvious over Winskill et al. (Applied Animal Behaviour Science vol. 48, pp. 25-35 (1996)).

The Examiner alleges that the composition of Winskill that is administered to the horse would inherently produce the effect of treatment or amelioration of animal stereotypy or minimization of the risk of the horse developing stereotypy. In the alternative, the Examiner acknowledges that Winskill does not disclose treatment or amelioration of animal stereotypy, but asserts that oral administration of the composition of Winskill comprising fibre and oil would

intrinsically produce the effects expected from the composition thereby allegedly rendering the process of claim 34 obvious.

To address the rejection of claim 34, Applicants propose to delete the reference in claim 34 to “minimizing the risk of an animal developing animal stereotypy.” Winskill acknowledges that none of the horses used for the experiments described were seen to perform stereotypic behaviour (Winskill, page 34, lines 3-4). Because Winskill does not disclose administering a composition to an animal exhibiting stereotypy, Winskill does not recite all the elements of claim 34 either explicitly or inherently, and so does not anticipate amended claim 34. Since there is no link in the cited prior art between stomach acidity and animal stereotypy, amended claim 34 is not obvious over Winskill.

Claims 12-17, 20-23, 28-30, and 34 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Winskill (Office Action, page 11). Claims 11 and 34 are patentable over Winskill for the reasons stated above—that there is no teaching in the reference to treat or prevent stereotypy. The dependent claims are allowable at least by virtue of their dependency on these independent claims. Applicants submit that none of said claims can be deemed obvious where it was not known that stereotypy was related to the acidity of the intestinal tract.

C. Pagan

Claims 24 and 25 stand rejected under 35 U.S.C. § 102(a) for allegedly being anticipated by or alternatively under 35 U.S.C. § 103(a) for allegedly being obvious over Pagan (Australian Equine Journal vol. 16(4), pp. 159-161 (1998)). Applicants respectfully traverse.

The Examiner alleges that since the method of treatment or amelioration of animal stereotypy involves reduction or minimization of ulcers, then by treating or minimizing ulcers in the horse the effect of treatment or amelioration of animal stereotypy would inherently

be produced. Alternatively, the Examiner acknowledges that Pagan does not specifically say treatment or amelioration of stereotypy, but asserts that treatment and minimization or prevention of gastric ulcer by Pagan would intrinsically treat or ameliorate stereotypy in the horse thereby allegedly rendering the claimed process obvious.

It has been pointed out to the Examiner in several of the Applicants' previous responses that there is no disclosure in the cited prior art of a link between gastric ulcers and performance of animal stereotypy, and the Examiner has failed to demonstrate any such link. In the absence of any such link, it was not obvious at the time of the invention to expect that minimizing, reducing or treating ulcers would treat or ameliorate animal stereotypy, or minimize the risk of development of animal stereotypy.

D. Lambert in view of Brever

Claims 1, 2 and 7 stand under 35 U.S.C. § 103(a) for allegedly being obvious over Lambert et al. in view of Brever et al. (U.S. Patent No. 3,946,115).

The Examiner acknowledges that Lambert does not describe the size of the wheat or rolled oats, but asserts that horse feeds are generally extruded and when extruded have the length disclosed in Brever of from 1/8inch to 3 inches. As explained above, Lambert does not disclose that at least some of the fibre in the composition is chopped fibre. The Applicants also do not agree that horse feeds are generally extruded. In the Applicants' experience, it was normal practice at the priority date of the present invention to mix and pellet components of horse feed, but not general practice to extrude the feed. Brever disclose that the extruded product is preferably cut into pellets having a length of about one-half inch (column 6, lines 48-50). However, there is no disclosure that fibre in the pellet is chopped fibre that is about 1-7cm long. The process described in Brever involves mixing and finely grinding proteinaceous, farinaceous,

fibrous and other nutritional materials before extrusion (column 2, lines 23-25). The farinaceous-proteinaceous fibrous ingredients are ground to a particle size of less than 0.070 inch (i.e. 0.18cm) before adding water and blending the mixture prior to extrusion (column 5, lines 40-49). Thus, the fibre may be considerably less than 1cm long before extrusion as a result of the grinding process. There is no disclosure in Brever that the fibre present in the extruded horse feed includes chopped fibre that is about 1-7cm long, and so the combination of cited references does not render the claimed subject matter obvious.

E. Lambert in view of Pagan

Claims 1, 2, 9-11, 17 and 18 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Lambert et al. in view of Pagan.

As explained above, there is no disclosure in either Lambert or Pagan that at least some of the fibre present in the composition is chopped fibre (Claims 1 and 2). Thus, there is no combination of the cited references that would render the subject matter unpatentable as obvious. With respect to claims 17 and 18, which depend from claims 11 or 34, neither Lambert nor Pagan teaches the link between stomach acidity and stereotypy, as discussed above. The subject matter of these dependent claims, relating to specific means of controlling stomach pH, is not made obvious by the combination of the two references.

F. Response to Arguments

The prior art does not teach a connection between stomach acidity and stereotypy. the Examiner alleges that it is known in the art that gastric discomfort leads to stereotypic behaviour such as crib-biting and wood chewing, citing Burkard. However, according to the Notice of References Cited accompanying the action, Burkard was published on January 3, 2008 (although no publication date appears on the reference), which is several years after the earliest

priority date of the present invention. There is no evidence from this document that it was known at the priority date of the present application that gastric discomfort leads to stereotypic behaviour. The prior art does not show the link asserted by the Examiner. Burkard is not prior art. The link between gastric acidity and stereotypy is not found in any cited prior art having a date prior to Applicants' priority date. Nor is any such reference known to the Applicants. Since Burkard was published several years after the priority date of the present application, it is of no relevance to the patentability of the claimed invention.

G. Dr. Patricia Harris Declarations

Applicants submit that the Declaration of Dr. Harris, dated April 29, 2008, has not been properly considered.

The Examiner alleges, citing Johnson, that it is known in the art that administration of sodium carbonate lowers the incidence of stereotypy, and asserts that this is a suggestion that sodium bicarbonate would lower the incidence of stereotypy. The Examiner fails to address the fact that oral administration of sodium carbonate and sodium bicarbonate was not known or suggested for treatment of stereotypy and that this would not have been obvious to one of ordinary skill. The Applicants have explained in several previous responses that Johnson discloses that neutralising the acidity of the hind-gut by administering sodium carbonate to the caecum lowered the incidence of stereotypic behaviour (referring to work by Willard et al 1977 in which sodium carbonate was administered by caecal infusion). Johnson does not teach or suggest oral administration of sodium carbonate to horses (Declaration of Dr. Harris of April 29, 2008). To the contrary, Dr. Harris has presented evidence on the record against the oral use of sodium bicarbonate or sodium carbonate to cause a reduction in hindgut acidity. Dr. Harris confirms in her Declaration of April 29, 2008, that the person of ordinary skill in the art would

not in her opinion have included carbonate in the feed of horses in order to treat stereotypy.

Thus, the Office Action avoids, or glosses over, a central fact issued raised in the Declaration.

Specifically, the prior art does not teach oral administration of sodium carbonate to treat stereotypy, only caecal administration to reduce hindgut acidity. Dr. Harris's Declarations present evidence that the skilled person would not in her opinion have included carbonate in the feed of horses to reduce hindgut acidity. Thus, the skilled person would not have had the requisite reasonable expectation of success that addition of sodium carbonate to the feed of Winskill would lower the incidence of stall-walking (or other stereotypy).

At point (vi) of paragraph 37, the Examiner alleges that the evidence provided by the applicant on October 6, 2006 would not have taught away from including sodium carbonate in a feed for horses because Winskill allegedly teaches that food containing protein and fibre and fat lowers fecal acidity and reduces stereotypy/stall-walking. However, there is no such disclosure in Winskill relating to fecal acidity. Indeed, Winskill acknowledges that none of the horses used for the experiment described were seen to perform stereotypic behaviour (page 34, lines 4-5). Moreover, Dr. Harris's October 6, 2006 declaration specifically presented evidence that the literature reported a negative correlation of feed pH and fecal pH (see paragraph 10 of the October 6, 2006 declaration). Dr. Harris also pointed to the observation in the literature that sodium carbonate and sodium bicarbonate would be expected to be neutralized in the stomach. The declaration also states that identification of a link between hindgut acidity and stereotypy in the horse does not in Dr. Harris's opinion mean there is also necessarily a link between stomach acidity and stereotypy (and differences between the hindgut and stomach of the horse are described, with supporting evidence). Thus, contrary to the Examiner's assertion, the declarations of Dr. Harris, taken together, do not support the assertion that oral administration of

sodium carbonate or the addition of sodium carbonate to the feed of Winskill to reduce stall-walking/stereotypy would have been obvious.

At paragraph 38 on page 16, the Examiner asserts that the declaration has not provided factual evidence as to why sodium carbonate cannot be administered orally to the horse, and alleges in paragraphs 39 and 40 that it is known from Lambert et al to administer antacid such as calcium carbonate to horses. As explained above, the skilled person would not have combined sodium carbonate with the feed of Winskill with the requisite reasonable expectation that the resulting composition would be suitable for treatment of stereotypy. In view of this, the skilled person would not have made a composition within the scope of claim 1 or 2.

Evidence that a feed containing fat, fibre and Neigh-Lox (which contains sodium carbonate) lowers stereotypy is presented in Example 1 in the present application. This is hardly surprising as Example 1 is an example within the scope of the invention. The burden is on the Examiner to show that this was in the prior art, or was obvious in view of the prior art. The Office Action has failed to establish this.

CONCLUSION

In sum, nothing in the cited art is believed to teach or suggest either a link between stomach acidity and stereotypy generally or providing a composition with a stomach antacid, fat and fiber as specifically recited in the present claims. It is also clear from the Harris April 29, 2008, Declaration that the skilled person would not have treated or reduced ulcer formation or controlled stomach pH to treat, ameliorate, or minimize the risk of stereotypy. Based on the foregoing, Applicants therefore submit that claims 1, 2, 11, 24, and 34, together with the claims dependent thereon, are patentable over the cited art. Accordingly, withdrawal of the present rejections is kindly requested.

Wherefore, it is respectfully submitted that the presently claimed invention is not disclosed or suggested by the art of record whether taken alone or together. Accordingly, it is respectfully requested that the claims be allowed and the case passed to issue.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

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